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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/512,109	07/21/2005	Mitsuo Nishikawa	051023-0118	4547

22428 7590 07/13/2007  
FOLEY AND LARDNER LLP  
SUITE 500  
3000 K STREET NW  
WASHINGTON, DC 20007

EXAMINER

BUNNER, BRIDGET E

ART UNIT	PAPER NUMBER
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1647

MAIL DATE	DELIVERY MODE
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07/13/2007

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/512,109	<b>Applicant(s)</b> NISHIKAWA, MITSUO	
	<b>Examiner</b> Bridget E. Bunner	<b>Art Unit</b> 1647	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 19 September 2005.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-14 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1-14 are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                       | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input checked="" type="checkbox"/> Other: <u>Appendix A</u>                         |

## **DETAILED ACTION**

### ***Status of Application, Amendments and/or Claims***

The amendment of 21 October 2004 has been entered in full. Claims 1-13 are amended.  
Claim 14 is added.

### ***Election/Restrictions***

1. Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s) 1-5, drawn to a DNA coding for a polypeptide, an expression vector, and host cell.

Group II, claim(s) 6-8 and 13-14, drawn to a polypeptide.

Group III, claim(s) 9, drawn to a monoclonal antibody which binds the polypeptide.

Group IV, claim(s) 10-12, drawn to a method for supporting hematopoietic stem cell or hematopoietic progenitor cell proliferation or survival.

2. The inventions listed as Groups I-IV do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

This PCT rule defines special technical features as technical features that identify a contribution which each of the claimed inventions, considered as a whole, makes over prior art. Claim 1 is anticipated by prior art. Warren et al. (WO/0260942) teach an isolated DNA sequence that encodes a polypeptide that is 99.5% identical to SEQ ID NO: 48 of the instant application (see sequence alignment attached to the instant Office Action as Appendix A; see SEQ ID NO: 28 of Warren et al.). Therefore, claim 1 lacks a special technical feature and cannot share one with the other claims.

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention or species may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

Should applicant traverse on the ground that the inventions or species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions or species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C.103(a) of the other invention.

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and the product claims are subsequently found allowable, withdrawn process claims that depend from or otherwise require all the limitations of the allowable product claim will be considered for rejoinder. All claims directed to a nonelected process invention must require all the limitations of an allowable product claim for that process invention to be rejoined.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully

Art Unit: 1647

examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103 and 112. Until all claims to the elected product are found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained.

Withdrawn process claims that are not commensurate in scope with an allowable product claim will not be rejoined. See MPEP § 821.04(b). Additionally, in order to retain the right to rejoinder in accordance with the above policy, applicant is advised that the process claims should be amended during prosecution to require the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.** Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bridget E. Bunner whose telephone number is (571) 272-0881. The examiner can normally be reached on 8:30-4:30 M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Nickol can be reached on (571) 272-0835. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

BEB  
Art Unit 1647  
06 July 2007

*Bridget E. Bunner*

**BRIDGET BUNNER  
PATENT EXAMINER**

Appendix A

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<!--StartFragment-->RESULT 6
ABS58379
ID   ABS58379 standard; DNA; 1125 BP.
XX
AC   ABS58379;
XX
DT   05-NOV-2002 (first entry)
XX
DE   Protein modification and maintenance molecule #12.
XX
KW   Protein modification and maintenance molecule; gastrointestinal disorder;
KW   dysphagia; esophageal spasm; gastritis; anorexia; nausea; hypertension;
KW   cardiovascular disorder; atherosclerosis; vasculitis; aneurysm; allergy;
KW   ischaemic heart disease; autoimmune disorder; inflammatory disorder;
KW   acquired immunodeficiency syndrome; AIDS; ankylosing spondylitis; cancer;
KW   anaemia; amyloidosis; cell proliferative; arteriosclerotic bursitis;
KW   cirrhosis; developmental disorder; renal tubular acidosis; anaemia;
KW   bone resorption; epilepsy; epithelial disorder; keratosis pilaris;
KW   allergic contact dermatitis; insect bite; keloid; dermatofibroma; eczema;
KW   neurological disorder; stroke; cerebral neoplasm; Alzheimer's disease;
KW   Huntington's disease; dementia; reproductive disorder; infertility;
KW   endometriosis; gynecomastia; ectopic pregnancy; gene therapy; gene; ss.
XX
OS   Homo sapiens.
XX
PN   WO200260942-A2.
XX
PD   08-AUG-2002.
XX
PF   30-JAN-2002; 2002WO-US002813.
XX
PR   31-JAN-2001; 2001US-0265705P.
PR   05-FEB-2001; 2001US-0266762P.
PR   16-FEB-2001; 2001US-0269581P.
PR   23-FEB-2001; 2001US-0271198P.
PR   01-MAR-2001; 2001US-0272813P.
PR   13-MAR-2001; 2001US-0275586P.
PR   23-MAR-2001; 2001US-0278505P.
PR   30-MAR-2001; 2001US-0280539P.
XX
PA   (INCY-) INCYTE GENOMICS INC.
XX
PI   Warren BA, Honchell CD, Lu Y, Walia NK, Burford N, Delegeane AM;
PI   Gandhi AR, Baughn MR, Griffin JA, Gietzen KJ, Lu DAM, Ison CH;
PI   Ramkumar J, Tang TY, Lal PG, Borowski ML, Duggan BM, Hafalia AJA;
PI   Arvizu C, Thangavelu K, Yao MG, Elliott VS, Ding L, Yue H, Lee S;
PI   Swarnakar A, Tran UK, Xu Y;
XX
DR   WPI; 2002-608499/65.
DR   P-PSDB; ABG76508.
XX
PT   New protein modification and maintenance molecules useful for treating or
PT   preventing gastrointestinal, cardiovascular, autoimmune/inflammatory,
PT   cell proliferative, developmental, neurological and reproductive
PT   disorders.
XX
PS   Claim 5; Page 168-169; 172pp; English.
XX
CC   The invention describes an isolated human polypeptide (I), a naturally
CC   occurring amino acid sequence at least 90 % identical to the protein, or
CC   a biologically active fragment or an immunogenic fragment of the protein.
CC   The protein modification and maintenance molecules are useful in the
CC   diagnosis, treatment, and prevention of gastrointestinal (e.g. dysphagia,
CC   esophageal spasm, gastritis, anorexia or nausea), cardiovascular (e.g.
CC   atherosclerosis, hypertension, vasculitis, aneurysms, or ischaemic heart
CC   disease), autoimmune/inflammatory (e.g. acquired immunodeficiency
CC   syndrome (AIDS), allergies, ankylosing spondylitis, anaemia or
CC   amyloidosis), cell proliferative (e.g. cancers, arteriosclerotic,
CC   bursitis, or cirrhosis), developmental (e.g. renal tubular acidosis,
CC   anaemia, bone resorption, or epilepsy), epithelial (e.g. allergic contact
CC   dermatitis, keratosis pilaris, insect bites, keloid, dermatofibroma or
CC   eczema), neurological (e.g. stroke, cerebral neoplasms, Alzheimer's
CC   disease, Huntington's disease or dementia), and reproductive disorders
CC   (e.g. infertility, endometriosis, gynecomastia or ectopic pregnancy).
CC   These may also be used in assessing the effects of exogenous compounds on
CC   the expression of nucleic acid and amino acid sequences of protein

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Appendix A  
(cont.)

CC modification and maintenance molecules. Polynucleotides are useful in  
 CC somatic and germline gene therapy. This sequence encodes a protein  
 CC modification and maintenance molecule described in the invention  
 XX  
 SQ Sequence 1125 BP; 296 A; 274 C; 311 G; 244 T; 0 U; 0 Other;

## Alignment Scores:

Pred. No.:	7.03e-109	Length:	1125
Score:	1374.00	Matches:	242
Percent Similarity:	99.6%	Conservative:	0
Best Local Similarity:	99.6%	Mismatches:	1
Query Match:	99.5%	Indels:	0
DB:	6	Gaps:	0

US-10-512-109-48 (1-243) x ABS58379 (1-1125)

```

Qy      1 MetGlnPheArgLeuPheSerPheAlaLeuIleIleLeuAsnCysMetAspTyrSerHis 20
      |||
Db     311 ATGCAGTTTCGCCTTTTCTCCTTGCCCTCATCATTCTGAAGTGCATGGATTACAGCCAC 370

Qy     21 CysGlnGlyAsnArgTrpArgArgSerLysArgAlaSerTyrValSerAsnProIleCys 40
      |||
Db     371 TGCCAAGGCAACCGATGGAGACGCAGTAAGCGAGCTAGTTATGTATCAAATCCCATTTGC 430

Qy     41 LysGlyCysLeuSerCysSerLysAspAsnGlyCysSerArgCysGlnGlnLysLeuPhe 60
      |||
Db     431 AAGGGTTGTTTGTCTTGTTCAAAGGACAATGGGTGTAGCCGATGTCAACAGAAGTTGTTC 490

Qy     61 PhePheLeuArgArgGluGlyMetArgGlnTyrGlyGluCysLeuHisSerCysProSer 80
      |||
Db     491 TTCTCTCTCGAAGAGAAGGGATGCGCCAGTATGGAGAGTGCCTGCATTCTGCCCATCC 550

Qy     81 GlyTyrTyrGlyHisArgAlaProAspMetAsnArgCysAlaArgCysArgIleGluAsn 100
      |||
Db     551 GGGTACTATGGACACCGAGCCCCAGATATGAACAGATGTGCAAGATGCAGAATAGAAAAC 610

Qy    101 CysAspSerCysPheSerLysAspPheCysThrLysCysLysValGlyPheTyrLeuHis 120
      |||
Db     611 TGTGATTCTTGCTTTAGCAAAGACTTTTGTACCAAGTGCAAAGTAGGCTTTTATTGTCAT 670

Qy    121 ArgGlyArgCysPheAspGluCysProAspGlyPheAlaProLeuGluGluThrMetGlu 140
      |||
Db     671 AGAGGCCGTTGCTTTGATGAATGTCCAGATGGTTTGCACCATTAGAAGAAACCATGGAA 730

Qy    141 CysValGluGlyCysGluValGlyHisTrpSerGluTrpGlyThrCysSerArgAsnAsn 160
      |||
Db     731 TGTGTGGAAGGATGTGAAGTTGGTCATTGGAGCGAATGGGGAAGTTGTAGCAGAAATAAT 790

Qy    161 ArgThrCysGlyPheLysTrpGlyLeuGluThrArgThrArgGlnIleValLysLysPro 180
      |||
Db     791 CGCACATGTGGATTTAAATGGGGTCTGGAAACAGAACACGGCAAATTGTTAAAAGCCA 850

Qy    181 ValLysAspThrIleLeuCysProThrIleAlaGluSerArgArgCysLysMetThrMet 200
      |||
Db     851 GTGAAAGACACAATACCGTGTCCAACCATGCTGAATCCAGGAGATGCAAGATGACAATG 910

Qy    201 ArgHisCysProGlyGlyLysArgThrProLysAlaLysGluLysArgAsnLysLysLys 220
      |||
Db     911 AGGCATTGTCCAGGAGGGAAGAGAACACCAAAGGCGAAGGAGAAGAGGAACAAGAAAAAG 970

Qy    221 LysArgLysLeuIleGluArgAlaGlnGluGlnHisSerValPheLeuAlaThrAspArg 240
      |||
Db     971 AAAAGGAAGCTGATAGAAAGGGCCCAGGAGCAACACAGCGTCTTCCTAGCTACAGACAGA 1030

Qy    241 AlaAsnGln 243
      |||
Db    1031 GCTAACCAA 1039
<!--EndFragment-->

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